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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/187,661	11/06/1998	BRET A. SHIRLEY	5784-3	3329

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Chiron Corporation
Intellectual Property - R440
P.O. Box 8097
Emeryville, CA 94662-8097

EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 04/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/187,661

Applicant(s)

SHIRLEY ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,13,16-20 and 28-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,13,16-20 and 28-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Request for Continued Prosecution Application (CPA) filed on February 20, 2003 (Paper No. 29) under 37 CFR 1.53(d) is acknowledged. An action on the CPA follows.

Status of the Claims

2. Claims 1, 3, 4, 13, 16-20 and 28-44 are pending, and claims 1, 3, 4, 13, 16-20 and 28-44 are examined.
3. Formal drawings filed February 1, 2002 (Paper No. 24) is acknowledged.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 3, 4, 13, 16-20 and 28-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-9, 12-16 and 26-51 of copending Application No. 09/187,780 (See attached allowable claims). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 3, 4, 13, 16-20 and 28-44 in the instant application disclose a low salt-containing composition comprising biologically active human IGF-I or its functional variant in a concentration of about 250 mg/ml or greater, and at pH about 5.5 or greater, wherein the variant

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has at least 80% sequence identity to human IGF-I; and a cryogenically produced PLGA microsphere containing the composition. This is obvious in view of claims 2-9, 12-16 and 26-51 in the copending application which disclose a method of making microparticle comprising the step of providing a low salt-containing aqueous composition comprising biologically active human IGF-I or a biologically active analog thereof in a concentration of 250-500 mg/ml and a pH about 5.5 or greater, wherein the analog has at least 80% sequence identity to human IGF-I, and the microparticle is made at 2-8 °C. Since both sets of claims are directed to a low salt-containing aqueous composition comprising human IGF-I or a biologically active variant at a concentration of at least 250 mg/ml and a pH greater than 5.5. Thus, claims 1, 3, 4, 13, 16-20 and 28-44 in present application and claims 2-9, 12-16 and 26-51 in the copending application are obvious variations of a low salt-containing aqueous composition comprising human IGF-I or a biologically active variant thereof at a concentration of at least 250 mg/ml and a pH about 5.5 or greater, wherein the variant has at least 80% sequence identity to human IGF-I.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1, 3, 4, 13, 16-20 and 28-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-40, 44-48, 85-93, 97-107, 111 and 112 of copending Application No. 09/188,051. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 3, 4, 13, 16-20 and 28-44 in the instant application disclose a low salt-containing aqueous composition comprising biologically active human IGF-I or a functional variant thereof in a concentration of at least 250 mg/ml and a pH about 5.0 or greater, wherein the variant has at least

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80% sequence identity to human IGF-I. This is obvious in view of claims 29-40, 44-48, 85-93, 97-107, 111 and 112 in the copending application which disclose a composition having a pH of 5.5 or greater, comprising IGF-I or a biologically active analog thereof having at least 70% sequence identity to human IGF-I at a concentration of 12 mg/ml or greater, and at a temperature of about 4 °C, and a solubilizing compound comprising a guanidinium group, wherein the solubilizing compound is in an amount sufficient to make IGF-I or analog thereof soluble. Since the low salt-containing composition can be a composition containing a salt such as arginine or other arginine compounds in an amount that makes IGF-1 or its analog more soluble at higher concentration and at about 4 °C, thus, both sets of claims encompass a low salt-containing (e.g., arginine) aqueous composition comprising human IGF-I or a biologically active variant thereof at a concentration of at least 250 mg/ml and a pH about 5.5 or greater, wherein the variant has at least 80% sequence identity to human IGF-I. Thus, claims 1, 3, 4, 13, 16-20 and 28-44 in present application and claims 29-40, 44-48, 85-93, 97-107, 111 and 112 in the copending application are obvious variations of a low salt-containing (e.g., arginine) aqueous composition comprising human IGF-I or a biologically active variant thereof at a concentration of at least 250 mg/ml and a pH about 5.5 or greater, wherein the amount of arginine compound makes IGF-I or its analog more soluble at about 4 °C.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 1, 3, 4, 13, 16-20 and 28-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 1, 3, 4, 13, 16-20 and 28-44 are indefinite because of the use of the term “at least about 250 mg/ml” or “greater than about pH 5.0”. The term “at least about 250 mg/ml” or “greater than about pH 5.0” renders the claim indefinite; it is unclear whether the concentration is greater than 250 mg/ml as to “at least”, or less than 250 mg/ml as to “about”; and whether the pH is higher than 5.5 as to “greater than”, or less than 5.5 as to “about”. Claims 3, 4, 13, 16-20, 28-33, 35-41, 43 and 44 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend. Use of the terms “about 250 mg/ml or greater” and “about pH 5.0 or greater” is suggested.

8. Claims 16, 38, 40 and 43 are indefinite because of the use of the term “and/or”. The term “and/or” renders the claim indefinite, it is unclear whether the limitation after “and/or” is included or not, and if included is to be read as an alternative “or” or the conjunctive “and”.

9. Claims 19, 39 and 44 are indefinite, it is unclear what the term “PLGA” means. A fully spelled out word should be indicated at the first occurrence.

Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

April 16, 2003

Christopher S. F. Low
**CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**